



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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April 18, 2018

Re: Animal Welfare Assurance
A4051-01 [OLAW Case U]

Ms. V. Kay Holt
Deputy Director, National Health and
Environment Effects Research Laboratory
U.S. Environmental Protection Agency
EPA-MD-B305-01, 109 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Ms. Holt,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 17, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the EPA National Health and Environmental Effects Research Laboratory, following up on an initial telephone report on March 8, 2018. According to the information provided, OLAW understands that due to problems with the electronic animal procurement system, more rats than approved on the protocol were ordered and received.

The immediate action taken upon discovery consisted of cancelling the pending order. The protocol was amended to account for the additional rats, a spread sheet will be used to track animals, animal users have been alerted to the problem and advised to use spread sheets, and a new animal procurement and tracking system is under development.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
National Health and Environmental Effects Research Laboratory
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

April 17, 2018

Dr. Brent Morse, Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive, MSC-7982
Bethesda, MD 20892-7982

Dear Dr. Morse:

The purpose of this letter is to describe a non-compliance issue at our institution (OLAW Assurance number: A4051-01), which was identified March 5, 2018, and to inform your office of the IACUC's disposition of the issue. Your office was given a preliminary notification of the incident via telephone contact to Dr. Axel Wolff from our IACUC Chair (Dr. Michael G. Narotsky) on March 8, 2018.

The non-compliance involves flaws in our electronic animal procurement system and, consequently, a principal investigator's (PI's) laboratory ordering and receiving more rats than authorized on their IACUC-approved protocol. An explanation of the incident and corrective actions taken by the PI and the IACUC are provided below.

Our in-house electronic animal procurement system allows each PI (or designate) to place animal requests toward their IACUC-approved protocol. With each request, the system presents an accounting of the animals authorized and already shipped on the protocol, and, theoretically, precludes users from ordering more animals than the protocol is authorized to receive. However, the system is flawed in that it does not properly account for animals transferred to the protocol, nor for animals ordered, but not yet received. Both flaws came into play recently when the PI's laboratory manager placed three orders in quick succession. The system showed that the protocol seemingly had an allowance of 47 animals to order, but had only 2 animals left to order (because it was not accounting for a previous transfer, nor was it accounting for a pending shipment from a previous order). Subsequently, the system allowed receipt of the shipment from the previous order as well as two of the three shipments from the most recent order. The system *did* recognize the pending arrival of the final shipment as going over the authorized limit and triggered a partial cancelation of the order, alerting the PI. At this point, the laboratory manager promptly alerted the Animal Research Program Office (ARPO) and the remaining order was immediately cancelled. The PI promptly amended the protocol to increase animal numbers and to justify the additional animals; the IACUC reviewed and approved the amendment on March 12, 2018, and the protocol has been brought back into compliance.

To prevent recurrences of this type of noncompliance, the PI and lab manager have developed a spreadsheet to better track animal usage for each of their animal protocols. Furthermore, the IACUC Chair has alerted the other animal researchers of the flaws in the animal procurement system and shared examples of animal-tracking spreadsheets that may be used to better track animal usage. Finally, a new animal procurement system is under development to replace the current flawed system and roll-out is expected in FY2019.

We hope these measures satisfactorily address the issue. Please contact Michael Narotsky **Exemption 6**) if you have any questions or comments.

Sincerely,



V. Kay Holt
Deputy Director, NHEERL
Institutional Official



Michael G. Narotsky, PhD
NHEERL IACUC Chair

cc:

Dr. Leslie Jarrell, Attending Veterinarian
Jaimie Graff, Director of Animal Resources Program Office
AAALAC, International



Initial Report of Noncompliance

By: *aw*

Date: *3/8/18*

Time: *PM*

Name of Person reporting: *Michael Narotsky IACUC chair*

Telephone #: **Exemption 6**

Fax #:

Email:

Name of Institution: *EPA*

Assurance number: *A4051*

Did incident involve PHS funded activity? ☐

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

PI ordered too many animals and went over approved number on protocol

Species involved: *?*

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Cancel order, amend protocol, use spread sheet to track numbers

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____